510(k) Summary
for the Anodyne™ Anterior Cervical Plate System

K132994/S001

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the Anodyne™ Anterior Cervical Plate System

1. GENERAL INFORMATION

Date Prepared: December 02, 2013

Trade Name: Anodyne™ Anterior Cervical Plate System

Common Name: Anterior cervical plate

DEC 0 5 2013

Classification Name: Spinal intervertebral fixation orthosis

Class: II

Product Code: KWQ

CFR section: 21 CFR section 888.3060

Device panel: Orthopedic

Legally Marketed Predicate Device: Anodyne™ Anterior Cervical Plate System (K121514)
UNIPLATE Anterior Cervical Plate System (K042544/ K082273/K100070)
CSLP Anterior Cervical Plate (Synthes - K000536)

Submitter: CoreLink, LLC
7606 Forsyth Blvd
Clayton, MO 63105

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2. DEVICE DESCRIPTION

The Anodyne™ Anterior Cervical Plate System is comprised of an assortment of cervical plates and screws that act to stabilize the spine during the intervertebral fusion process. The cervical plate has a rotatable anti-backout "lock" for each screw position to prevent back-out of the screw.

The plate is available in single and double plate configurations with multiple lengths ranging from 13 mm – 22 mm (1 level) and 26 mm – 40 mm (2 level) for the single plates. The double plates include 1 level (13 mm – 30 mm), 2 level (26 mm – 46 mm), 3 level (46 mm – 70 mm), and 4 level (60 mm – 100 mm). The screws are available in various lengths from 12 mm – 20 mm, with major thread diameter options of 4.6 mm or 5.2 mm.

Change from Predicate:

This 510(k) is submitted in order to gain clearance for the single plate configuration.

Materials:

Ti-6Al-4V alloy per ASTM F136

3. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The Anodyne™ Anterior Cervical Plate System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.

4. INTENDED USE

The Corelink ANODYNE™ Anterior Cervical Plate System is intended for anterior fixation of the cervical spine. Indications for use include the temporary stabilization of the anterior spine during the evolution of cervical fusions in patients with degenerative disc disease (DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions. The intended levels for treatment range from C2 – T1.

5. NON-CLINICAL TEST SUMMARY

The following tests were conducted:

- Static and dynamic compression per ASTM 1717
- Static torsion per ASTM F1717

The results of this testing indicate that the ANODYNE™ Anterior Cervical Plate System is equivalent to predicate devices.

6. CLINICAL TEST SUMMARY

No clinical studies were performed

7. CONCLUSIONS NONCLINICAL AND CLINICAL

CoreLink, LLC considers the ANODYNE™ Anterior Cervical Plate System to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 5, 2013

CoreLink, LLC
% Mr. J.D. Webb
OrthoMedix Group, Incorporated
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K132994
Trade/Device Name: Anodyne™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: October 7, 2013
Received: October 9, 2013

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132994/S001

Device Name
Anodyne™ Anterior Cervical Plate System

Indications for Use *(Describe)*
The CoreLink ANODYNE™ Anterior Cervical Plate System is intended for anterior fixation of the cervical spine. Indications for use include the temporary stabilization of the anterior spine during the evolution of cervical fusions in patients with degenerative disc disease (DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions. The intended levels for treatment range from C2 - T1.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices